

BALANCED SALT - calcium chloride, magnesium chloride, potassium chloride, sodium acetate, sodium chloride and sodium citrate solution

Akorn, Inc.

Rx only

DESCRIPTION

AKORN BALANCED SALT SOLUTION is a sterile physiological solution containing calcium chloride ($\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$), magnesium chloride ($\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$), potassium chloride (KCl), sodium acetate ($\text{C}_2\text{H}_3\text{NaO}_2 \cdot 3\text{H}_2\text{O}$), sodium chloride (NaCl) and sodium citrate ($\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot 2\text{H}_2\text{O}$). This solution is isotonic to ocular tissue and contains electrolytes required for normal cellular metabolic functions. Each 1 mL contains:

Calcium Chloride	(MW 147.02)	0.48 mg
Magnesium Chloride	(MW 203.31)	0.30 mg
Potassium Chloride	(MW 74.56)	0.75 mg
Sodium Acetate	(MW 136.08)	3.90 mg
Sodium Chloride	(MW 58.44)	6.40 mg
Sodium Citrate	(MW 294.10)	1.70 mg
Hydrochloric Acid and/or Sodium Hydroxide added to adjust pH.		
Water for Injection		

7.0 pH and 300 mosm/kg osmolality.

CLINICAL PHARMACOLOGY

Balanced Salt Solution is an isotonic solution for use in irrigating tissues of the eyes.

INDICATIONS AND USAGE

For use as an extraocular and intraocular irrigating solution during ocular surgical procedure involving perfusion of the eye with an expected maximum duration of less than 60 minutes.

CONTRAINDICATIONS

There are no specific contraindications for this preparation.

WARNINGS

- NOT FOR INJECTION OR INTRAVENOUS INFUSION.
- Do not use unless package is clear, seal is intact, container is undamaged.
- Do not use if product is discolored or contains a precipitate.
- SINGLE patient use only. The contents of this bottle should not be used in more than one patient.
- The use of additives with this solution may cause corneal decompensation.
- This solution contains no preservative; unused contents should be discarded.

PRECAUTIONS

Open under aseptic conditions only.

Prior to use, check the following: tip should be firmly in place, irrigating needle should be properly seated; squeeze out several drops before inserting into anterior chamber. The needle should be removed from the anterior chamber prior to releasing pressure to prevent suction.

Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.

There have been reports of corneal clouding or edema following ocular surgery in which Balanced Salt Solution (Sterile Irrigating Solution) was used as an irrigating solution.

ADVERSE REACTIONS

Irrigation or any trauma to the corneal endothelium may result in corneal swelling or bullous keratopathy.

Postoperative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

DOSAGE AND ADMINISTRATION

18 mL bottle

The adaptor plug is designed to accept an irrigating needle. Tissues may be irrigated by attaching the needle to the bottle as explained below. External irrigation may be done without the irrigating needle.

Method for Using Adaptor Plug for Ophthalmic Irrigating Needle

1. Aseptically remove bottle from pouch by peeling backing.
2. Snap-on surgeon's irrigating needle. Push until firmly in place.
3. Test assembly for proper function before use.

HOW SUPPLIED

18 mL bottle, NDC 17478-920-19

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid exposure to excessive heat and do not allow to freeze.

Akorn

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BS00N

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